



EPMF-ECHA meeting: completeness check on refinables and MISA

*Draft minutes, Meeting (Helsinki, ECHA)
15 May 2019*

1. Participants

France Capon (EPMF), Anna Daszynska (ECHA), Pawel Figiel (ECHA), Valérie Lasseigne-Phrakonkham (ECHA), Annika Mälkiä (ECHA), Jelle Mertens (EPMF), Jos Mossink (ECHA), Mercedes Viñas (ECHA)

2. Background

EPMF thanked ECHA for its availability and for having organized this meeting so quickly. France Capon introduced the topic explaining that in the context of the Brexit, the following three dossiers for Refinables (UVCB substances) have been updated with the only aim to transfer the Lead Registrant role from Johnson Matthey (a UK based company) to Heraeus: Material for reclaim, precious metals with or without support (EC 308-526-5); Materials for reclaim, precious metals in bricks, crucibles, trays, etc. (EC: 931-674-2) and Materials for reclaim, precious metals production by-products (EC 931-663-2). The three dossiers were updated for the last time in 2014, following the industry guidance on inorganic UVCBs existing at that time.

During the manual completeness check, failures have been identified mainly for substance identification (section 1.2) and the data waivers used for the following endpoints: Section 5.3.1 Bioaccumulation: aquatic/sediment, Section 5.4.1 Adsorption/desorption, Section 6.1.7 Toxicity to microorganisms, Section 6.3.1 Toxicity to soil macroorganisms except arthropods, Section 6.3.2 Toxicity to terrestrial arthropods, Section 6.3.3 Toxicity to terrestrial plants, Section 6.3.4 Toxicity to soil microorganisms. The deadlines set by ECHA for updating the 3 above mentioned dossiers are 3 September 2019, 4 September 2019 and 10 September, respectively. For information, a fourth Refinables dossier was ready for submission by another LR for the same reason (i.e. change of LR) but the process was stopped by EPMF and the new LR before submission to avoid the same situation.

Most of the issues raised in the communication from ECHA are well known to the metals' industry and are currently under discussion with ECHA in the context of MISA in order to find common and reliable solutions for all inorganic UVCBs.

However, the MISA discussion on UVCBs is only scheduled for October 2019 (i.e. one month after the deadlines set by ECHA for submission of the requested update). The EPMF and its members are therefore facing a difficult situation, having to preempt the discussions under MISA in order to comply with the ECHA requests to finalize the ongoing updates.

EPMF wanted to discuss with ECHA the best way forward to ensure from one hand that EPMF members comply with the ECHA requests but on the other hand to do the work in an efficient and correct way. Indeed, the aim is not to tweak the dossiers to ensure that it passes the manual completeness check but to have a viable and relevant solution which ensures that complete and compliant dossiers are submitted to ECHA.

ECHA presented the main issues raised in its communication to the Lead Registrant (see presentation in Annex), explaining in more details what the requirements are to have a complete dossier for UVCBs.



EPMF agreed that the substance identification issue could be addressed since the requirements presented by ECHA are similar to the most recent version of the Eurometaux guidance on UVCB registration and assessment (which still need to be discussed and agreed during the MISA process). However, for the data waivers (or the corresponding endpoint compliance in general), the situation is more difficult since the requirements presented by ECHA are not matching with the Assessment methodology developed by Eurometaux and followed by all the inorganic UVCB registrants.

3. Agreed way forward

ECHA and EPMF acknowledged that these issues cannot be resolved in a very short period of time. However, the importance to have compliant and meaningful dossiers passing the manual completeness check is recognised by both parties. In this respect, it is also important to address the issue of the waivers/endpoint filling and the access to the underlying experimental dataset in the context of the REACH requirements including dissemination. It is difficult at this stage of the process to identify a fixed deadline by when EPMF will be able to update the current submissions, taking into account the coming MISA discussions. ECHA clarified the implications of not updating these dossiers. The consequence will be the rejection of the current update. However, the registration will remain valid for the existing co-registrants and the change of LR can proceed and already be recorded in REACH-IT. The update of these three dossiers and of the fourth one (which will not be submitted now by the new LR) can then be submitted at a later stage to complete the process of changing the LR, i.e. at the time when the substance identification part of the industry "Guidance on risk assessment of inorganic UVCB under REACH" is agreed by ECHA and the assessment methodology of inorganic UVCBs will be discussed & agreed in the context of MISA. EPMF agreed that they will then not update the dossiers and they considered it as the best way forward and they committed to be diligent in developing an adequate UVCBs workplan to update the existing Refinables dossiers.

Mercedes Viñas also invited EPMF to proactively contact ECHA regarding any issues with IUCLID dossier preparation and completeness check, and to use the Contact form (<http://echa.europa.eu/contact>) to ensure that the reply is handled without delay.

EPMF thanked again ECHA for its time and the clarifications on the way forward.